



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

0301 04 FEB 14 10 40

AUG 31 2004

Mr. Peilin Guo
Vice President of Functional Foods
and Clinical Research
Jarrow Formulas
1824 South Robertson Boulevard
Los Angeles, California 90035

Dear Mr. Guo:

This is in response to your letter of March 11, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Jarrow Formulas is making the following claims, among others, for the product **Pomegranate Juice Concentrate**:

"[S]lows the normal progression of fatty streak build up in the arteries."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease, namely atherosclerosis. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

975-0163

LET 772

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'SJW', written over a horizontal line.

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

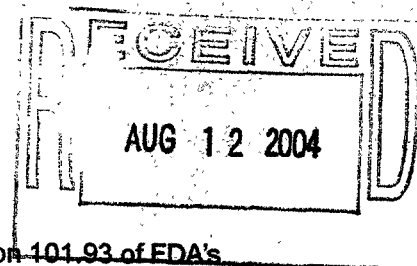
1824 South Robertson Blvd.
Los Angeles, CA 90035-4317
310/204-6936 • 800/726-0886
www.Jarrow.com

FAX NUMBERS
Orders 800/890-8955
General 310/204-2520
Administrative 310/204-5132

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810)
5100 Paint Branch Parkway
College Park, Maryland 20740
Reference phone #301-436-2373

July 2, 2004

Dear CFSA:



Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

(1) Name and Address of distributor:

Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035

(2) Statements:

Pomegranate Juice Concentrate is 4 times more concentrated in antioxidants than regular pomegranate juice. Only 1-2 tablespoons a day are necessary to capture pomegranate's health benefits. The Pomegranate (*Punica granatum*) has long been recognized as a fruit with many health benefits. Pomegranate tops all other conventional fruits, including blueberry and strawberry, in its ORAC (Oxygen Radical Absorbance Capacity) value, ranking pomegranate as one of the most powerful antioxidant fruits. Pomegranate juice contains a wide range of polyphenolic compounds, including ellagic and gallic acid, anthocyanins and tannins, especially punicalagin. Punicalagin is a powerful antioxidant, protecting cardiovascular function and accurate cellular replication. Clinical and experimental studies show that Pomegranate juice: Decreases Low Density Lipoprotein (LDL) oxidation and slows the normal progression of fatty streak build up in the arteries; Enhances cellular (macrophage) glutathione; Helps maintain regular platelet activity; Reduces activity of angiotensin converting enzyme (ACE); and supports normal vascular contraction; Promotes normal cell function and replication.
CAUTION: People on hypertensive medications should monitor their blood pressure closely when taking pomegranate juice. Those who are allergic to many plants should consult their physician before taking pomegranate or pomegranate products.

(3) Name of the dietary ingredient(s) if not provided in the text of the statement:

Pomegranate Juice Concentrate (*Punica granatum*, 65 Brix)

(4) Name of the dietary supplement(s):

Pomegranate Juice Concentrate

(5) The following disclaimer appears on the label in bold:

These statements have not been evaluated by the Food and Drug Administration.
This product is not intended to diagnose, treat, cure or prevent any disease.

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of the nutrients.

Respectfully submitted,

Peilin Guo, MS, RD
Vice President of Functional Foods and Clinical Research

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